JAN 1 5 2004

K032891 1/2

510(k) Summary of Safety and Effectiveness

In Accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: TranS1, Inc.
   Address: 1800 Sir Tyler Drive
   Suite 101
   Wilmington, NC 28405

   Phone; 910 509-3100
   Fax: 910 509-3101

   Contact: W. Allen Putnam
   Date of Summary Preparation: January 12, 2004

2. Name of Device: TranS1 Trans-Sacral Spinal Access and Preparation Device
   Generic Name: Rigid Endoscope and Instrument Set

3. Predicate Devices:

   AxiaMed, Inc., Trans-Sacral Spinal Access Device

   Surgical Dynamics, Inc., 30K Working Channel Scope and instrument kit

   Argus Medical Company Laparoscopic Discectomy Instrument System

   Surgical Dynamics, Inc., Nucleotome Tissue Aspirator/Cutter

   Surgical Dynamics, Inc., Nucleotome II Tissue Aspirator/cutter

   Sofamor Danek Mfg., Inc., Danek Tissue Cutting and Removal System

   United States Surgical, Auto Suture Spinal Elevator

   Harrington Spinal Elevator

   Karlin Technology, Inc., Cobb Spinal Elevator.

4. Device Description:

   The TranS1 Trans-Sacral Spinal Access and Preparation Device is for minimally invasive access to the anterior lower spine and consists of the following components:

Guide Pin Introducer
Guide Pins
Dilators
Dilators with sheath
Guide Pin Steering Handle
Twist Drills
Cutters
Brushs
Exchange Rod
Exchange Cannula
Brush Delivery Sleeve
Distraction Tool with driver
Bone Graft Inserter
Fibula Placement Tool

5. Indication for use:

The intended use of the TranS1 Trans-Sacral Spinal Access and Preparation Device is for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy or for assistance in the performance of L5-S1 interbody fusion.

6. Technological Characteristics of the Device:

The TranS1 Trans-Sacral Spinal Access and Preparation Device is designed to gain a minimally invasive access tract to the anterior region of the lower spine and assist in the diagnosis and treatment of the area. This would enable procedures such as biopsy, lumbar fusion, vertebroplasty, etc. The access devices are of such length that access up to L5 is possible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

TranS1, Inc.
c/o Mr. W. Allen Putnam
RCQ Strategies
6285 Chaska Road
Excelsior, Minnesota 55331

Re: K032891
Trade/Device Name: TranS1 Trans-Sacral Spinal Access and Preparation Kit
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: December 15, 2003
Received: December 16, 2003

Dear Mr. Putnam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032891

Device Name: TranS1 Trans Sacral Spinal Access and Preparation Kit

Indications For Use:

The intended use of the TranS1 Trans-Sacral Spinal Access and Preparation Device is for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy or for assistance in the performance of L5-S1 interbody fusion.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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